REMARKS

Claims 1 to 12 and 15 are under consideration. Claim 13 is cancelled. Claim 12, Independent claims 1, 11, and 14 and dependent claims thereof, are amended. Reconsideration of claims 1 to 12 and 14-15 is requested.

Applicant is also submitting a Declaration Under 37 C.F.R 1.132 by Dr. Rashida A. Karmali.

Claim Rejections- 35 USC § 103

Claims 1-15 were rejected as being unpatentable over Schramm et al. (5,935,864) in view of Nason (4,978,504) and further in view of White (4,214,874).

Page 2: The Action states "*Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. See figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers. The vial is sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. See column 4, lines 15-42. Capillary volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary*". (emphasis added)

In response, applicant agrees with the Action, that Schramm on its own is distinguishable from the present invention because it lacks the following four elements:

- 1) a filter in the container
- 2) does not describe the materials of construction
- 3) does not teach colorimetric analysis, and
- 4) does not teach a coated capillary.

Page 3, lines 4-21: *"Nason teaches a specimen test unit, see Figures 12-15. The device includes to (14) and bottom caps ((60) containing a swab sampling element (20) in a housing (30). The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection vial. The housing is made of plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one of ordinary skill in the art to modify Schramm to provide a plastic structure for deformability, and resiliency. With respect to caps, it would have been obvious to one having ordinary skill in the art to caps to seal the body structure of Schramm. With respect to filters it would have been obvious to one having ordinary skill in the art to modify the device of Schramm to include filters to trap components or provide reagents as suggested by Nason (column 8, lines 5-15). One would provide for colorimetric analysis within the test device in order to provide an easily understood analysis method of the contents inside to avoid transfer of materials from the device. This would safeguard the operator and provide a single use, self contained collection and analysis device.*

Scramm and Nason do not teach a coated capillary."(emphasis added)

In response, applicant agrees in part (part with emphasis) and disagrees in part.

In the interest of moving the prosecution forward, applicant has amended claims 1, 11, and 14 to distinguish the invention by including in the claims features that distinguish the filter membrane of the invention from filter membranes described in Nason.

Applicant agrees with the Action that the combination of Schramm and Nason still does not teach the coated capillary tube that is part of the collection device.

The Action relied on White and states:

Page 3: *"White teaches a capillary tube for blood collection (see column 2, line 51 through column 3, line 17). White teaches that the interior of the tube is coated with an anticoagulant. Capillary*

attraction is used to fill the tube with blood. It would be obvious to one having ordinary skill in the art to provide an anticoagulant coated on the interior of the capillary portion of the modified device of Schramm in order to minimize clotting from the sample being drawn through the capillary portion. Schramm and Nason include an immunoassay device. One would add the anticoagulant to ensure blood flow into the device. As for the graduated markings on the capillary, White also teaches these are conventional. It would have been obvious to one of ordinary skill in the art to add markings for volume.

In response applicant disagrees. White describes a collection tube having an anticoagulant, at least one resilient end cap for the tube having a cavity which extends well beyond the tube when a cap is in place, a magnetic element slidable within the tube and receivable in the cap and a magnet for shifting the magnetic element. In other words, White describes a capillary tube having an anticoagulant coating but the unique feature is the resilient cap. See claims 1 and 6 of White.

Present invention	Schramm	Nason	White
Filter membrane to filter fluid sample	XXXXX	3 filters in sequence distinguishable	XXXXX
Capillary collection coated	Capillary collection	XXXXX	Capillary collection Coated
XXXXX	XXXXX	XXXXX	Resilient cap
Collection/processing/ analysis/ Storage	Collection /XXX analysis	Collection/XXX analysis	Collection system XXX/XXX

Therefore, the combination of Schramm-Nason-White still does not overcome the unique features of the present invention of providing a disc-shaped, non-reacting filer membrane to filter the fluid sample, of providing a capillary tube attached to the barrel, and partly coated with reagents to process the sample and filter it, of having a continuous system to analyze the fluid sample using the analysis assembly housed in the device. See chart

above. This is because under MPEP 2141.02, in determining the differences between the prior art and the claims, the question under 35 USC 103, is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp. 713 F. 2d 1530 218 USPQ 871 (Fed. Cir. 1983). Under §103, secondary considerations as commercial success, long but unsolved needs, failure of others might be utilized . (discussed below).

The Action also states:

Claim 12 recites a plurality of containers having color-coded identifiers. Providing a plurality of containers to perform a number of different tests would have been obvious to one of ordinary skill in the art to provide increased throughput without any cross contamination.

In response, applicant agrees, because there are no available plurality of containers having color-coded identifiers on the market. This means that hospitals have to use individually wrapped containers. This is expensive and inefficient—in other words, there is a need for more cost effective and convenient availability of specimen collecting devices packages together.

The Examiner states on Page 6, that Declarations must be accompanied by evidence.

In response applicant submits Exhibit 1, a copy of the Catalog pricing for individually wrapped color-coded collection devices available in the market. See Declaration of Dr. Rashida Karmali, # 1.

From the supply chain point of view, an ordinary person skilled in the art would seriously consider purchasing packages of different –color coded containers packed together for the following reasons:1) it would enable collection, processing and analysis of samples of each patient (per tray or package) and reduce errors due to mix-up of samples, 2) a set of different color-coded containers would cost much less than buying individual containers in bulk as shown in Exhibit 1, 3) it would facilitate mass sample testing and throughput, 4) it would reduce errors in storing patient samples. There are no such color coded packages of tubes available on market based on Dr. Karmali's research and review of current vendors. See Declaration #2.

Therefore, under Graham v. John Deere, Co 383 U.S. 1, 148 USPQ 459 (1966), this rejection should

be withdrawn because the invention is unobvious under Scramm-Nason-White, meets a current need and will reduce cost.

Notice to the effect that claims 1-12 and 14-15 are allowable is respectfully requested.

Respectfully submitted,

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I hereby certify that this correspondence is transmitted by Express Class No. EQ 871632400US under 37 C.F.R. 1.10 on October 3, 2007 addressed to: Commissioner for Patents, Alexandria, VA 22313-1450.

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Signature

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